K002790

AUG - 6 2001

Summary of Safety and Effectiveness

Device Name: Add-on Condyle

Classification Name: Mandibular Condyle Prosthesis

Device Product Code: MPL (21 CFR 872-3960)

Intended Use:

Lorenz Add-on Condyle is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

Description:

The Add-On Condyle is attached to the Lorenz Reconstruction System Plate with two to three screws that insert through the plate and screw into the Condyle to secure it into place. The locking screws for the plate range from 2.4 - 2.7mm locking or self-tapping cortex screws. The plates are available in a wide variety of sizes and the Add-on Condyle is available in both right and left hands.

The Add-on Condyle is of the same general design, material, mechanical connection and function as marketed prior to the classification, using a Cobalt Chromium Condylar Head attached to a titanium plate with titanium screws.

Sterility Information:

The Add-on Condyle will be marketed as a non-sterile, single use device. Steam Sterilization recommendations are included in the package insert and can be seen in Attachment I.

Substantial Equivalence:

The Add-on Condyle is substantially equivalent to:

Synthes Locking Reconstruction Plate with Condyle K990637
Leibinger Condylar Prostheses

Contraindications:

- Infection
- Patient conditions where there is insufficient quantity or quality of bone to support the device.
- Patients with perforations in the mandibular fossa.
- Known allergic reactions to any of the materials used in the implant.

- Patients with mental or neurologic conditions who are unwilling or unable to follow postoperative care instructions.
- Skeletally immature patients.
- Patients presenting mental sensitivity reactions.

Warnings:
The following risks are associated with an Add-On Condyle:

- Implant loosening or displacement can occur.
- The screws used to anchor the implant may loosen causing changes in bite, difficulty in chewing, limited joint function and unpredictable wear on implant component.
- Implant breakdown may result in erosion or resorption of the glenoid fossa, which may result in intense pain.
- A foreign body reaction may occur resulting in implant deterioration and migration of materials.
- If the implant materials are unable to withstand mechanical loading, the implant can be worn, perforated, fragmented, fatigued or fractured resulting in failure of the device to function properly.
- Degenerative changes in the articular cartilage and or bone from disease or previous implants may lead to failure of this device.
- If the implant materials are subject to particulation or corrosion, toxic elements to various parts of the body.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2001

Mr. Trevor Byrd
Regulatory Assistant
Walter Lorenz Surgical, Incorporated
11520 Tradeport Drive
Jacksonville, Florida 32218-2480

Re: K002790
Trade/Device Name: Add-on Condyle
Regulation Number: 872.3960
Regulatory Class: III
Product Code: NEI
Dated: May 9, 2001
Received: May 10, 2001

Dear Mr. Byrd:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K002790

Device Name: Add-on Condyle

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002790